USE OF SIMULATION TO IMPROVE CARDIOVASCULAR STENT DEVELOPMENT

V. Astier, S. Bidal, V. Garitey, F. Mouret

Abstract :

A stent is a wire metal mesh tube placed into an artery or blood vessel to hold the structure open. The stent is collapsed to a small diameter and put over a balloon catheter. It's then moved into the area of the blockage. When the balloon is inflated, the stent expands, locks in place and forms a scaffold. This holds the artery open. The stent stays in the artery permanently, holds it open, improves blood flow to the heart muscle and relieves symptoms.

To optimize stent capabilities, the current design activity is aimed at improving uniform deployment, minimal recoil and foreshortening, maximal radial force, etc.

FE models were built to simulate realistic stent deployment for balloon expandable stents. The balloon is expanded accounting for balloon–stent interaction by applying a pressure on the inner surface of the balloon. Simulations allow to study the stent deployment and, then, the balloon is removed to study stent mechanical properties, like recoil.

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SIMULATION IN CARDIOVASCULAR DEVELOPMENT

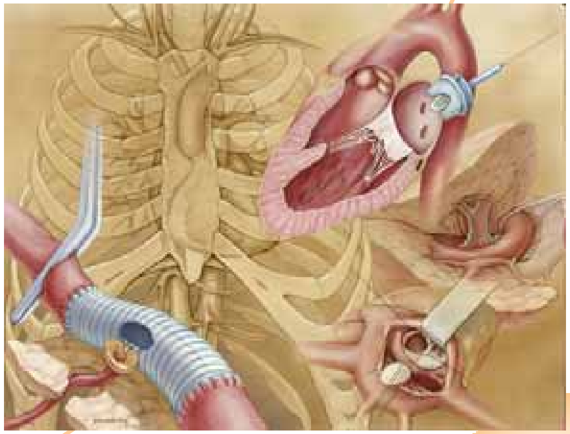
- **PROTOMED** is a product development company dedicated to **conceiving, developing** and **testing innovative medical devices**.

- It is located in the Marseille's University Hospital

- Team is composed of engineers and surgeons

- 2 main activities:
  - Medical device testing: - comparative testing,
    - FEA modeling,
    - feasibility testing,
    - validation testing,
    - custom validation.

  - Development services: conception and development of innovative medical devices



SIMULATION IN CARDIOVASCULAR DEVELOPMENT

What is a stent ?

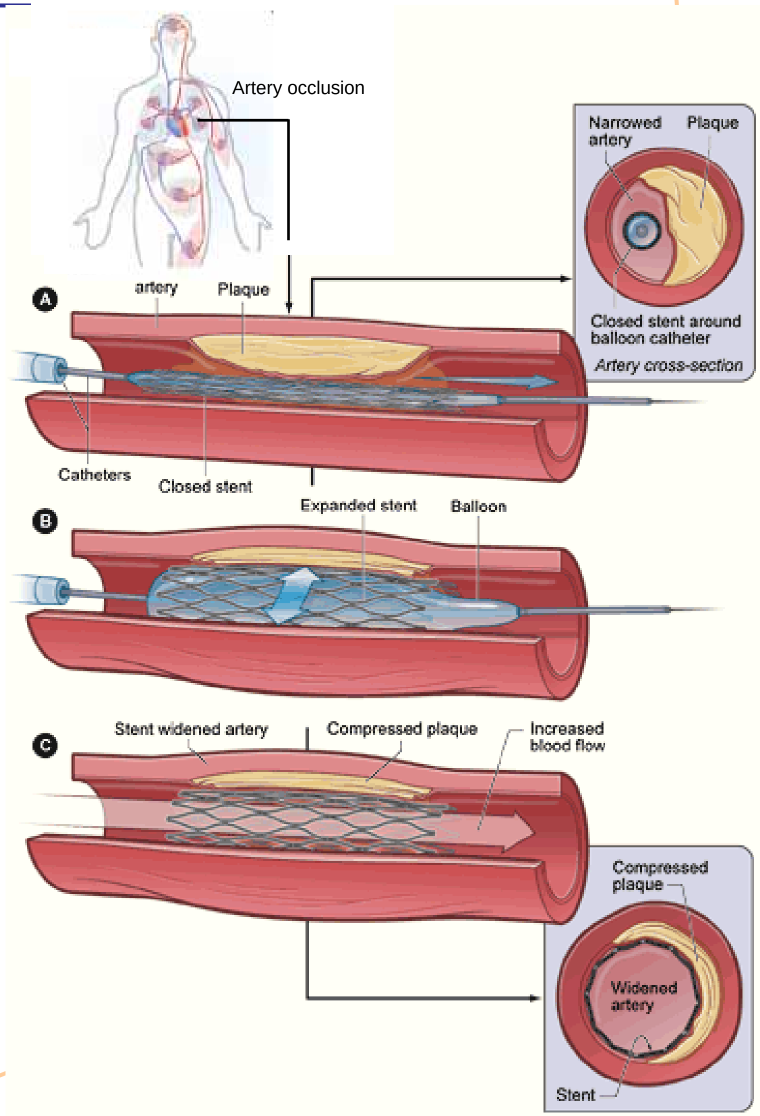
Vascular stents are wire mesh like structures, which are deployed in blocked arteries to restore the passage of the blood flow. By acting as a mechanical scaffold, stent usage is effective in preventing and treating artery occlusion.

- The stent is placed in the location of the plaque.

- The balloon is inflated with fluid. The stent expands and pushes of the plaque.

- The balloon is deflated and removed along with the elastic tube.

- The stent stays permanently deformed at the same location and aids for proper blood flow.



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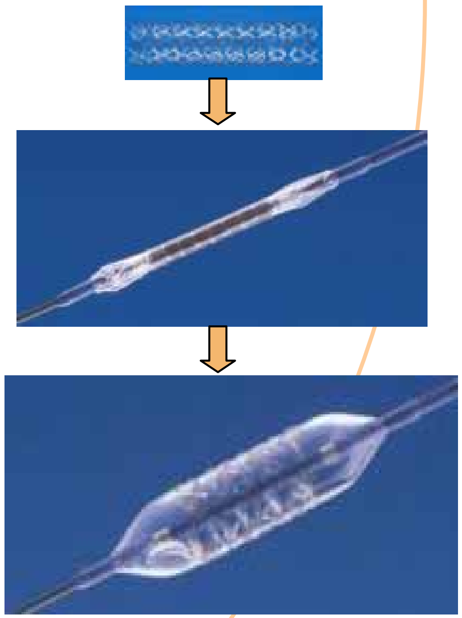
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

What are its mechanical properties ?

- The stent is obtained by laser cutting a hollow tube
- Then it is crimped tightly on the balloon
- At last, it is deployed in the blocked artery to restore the flow of blood through the vessel.

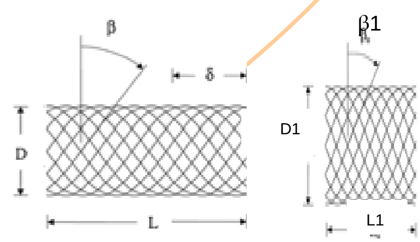
First plastic strain

Second plastic strain

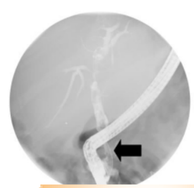


Needed characteristics:

- Biocompatibility and IRM visibility
- Good deformability and conformability (flexibility for acheminment)
- Important radial strength and scaffold
- Low recoil after plastic strain
- Low foreshortening to assure a precise placement



foreshortening



flexibility

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SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

How to improve its performance?

- stent design activity is aimed at improving
  - Uniform behaviour
  - No stress concentration
  - Recoil (lesser radial recoil)

- FE models were built to simulate realistic stent implantation process :

  - crimping

  - deployment with balloon

FE MODEL OF STENT →

CRIMPING SIMULATION

↓

Load simulation
Unload simulation } **With crimping tool**

↓

Results of crimped stent after spring back: **Uniform crimping**
Stress location
Recoil (%)

→

EXPANSION SIMULATION

↓

Expansion of balloon
Deflate / Unload the balloon } **Interface balloon-stent**

↓

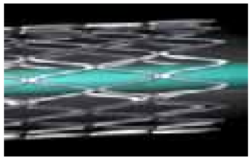
Results of expanded stent after spring back: **Uniform expansion**
Stress location
Recoil (%)

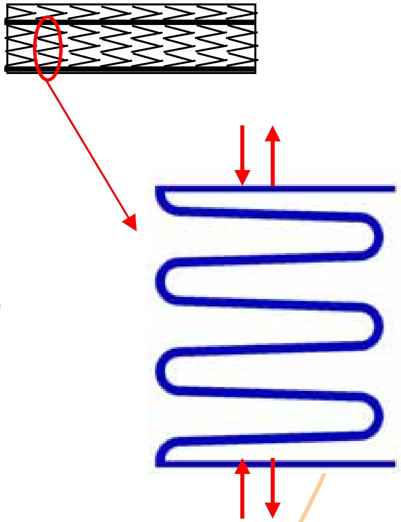
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

Methodology

2D study on one pattern

- CAO and design of stent in 2D with Hypermesh
- Configuration of the test with HyperCrash
- Simulation with Radioss solver
  - Compression
  - Relaxation (spring back)
  - Traction
  - Relaxation (spring back)



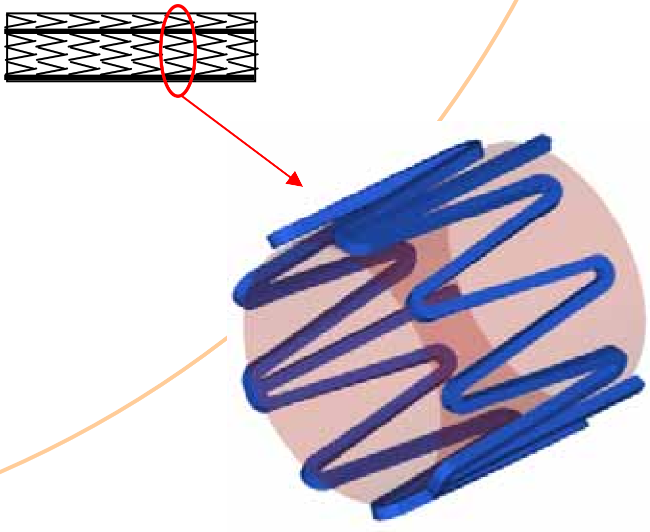


Optimisation in 2D

↓

3D study

- 3D design modification and configuration with HyperCrash
- Simulation with Radioss solver
  - Crimping in 3D (crimping tool)
  - Relaxation (spring back)
  - Inflation with a balloon (Pload function)
  - Relaxation (spring back)



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SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

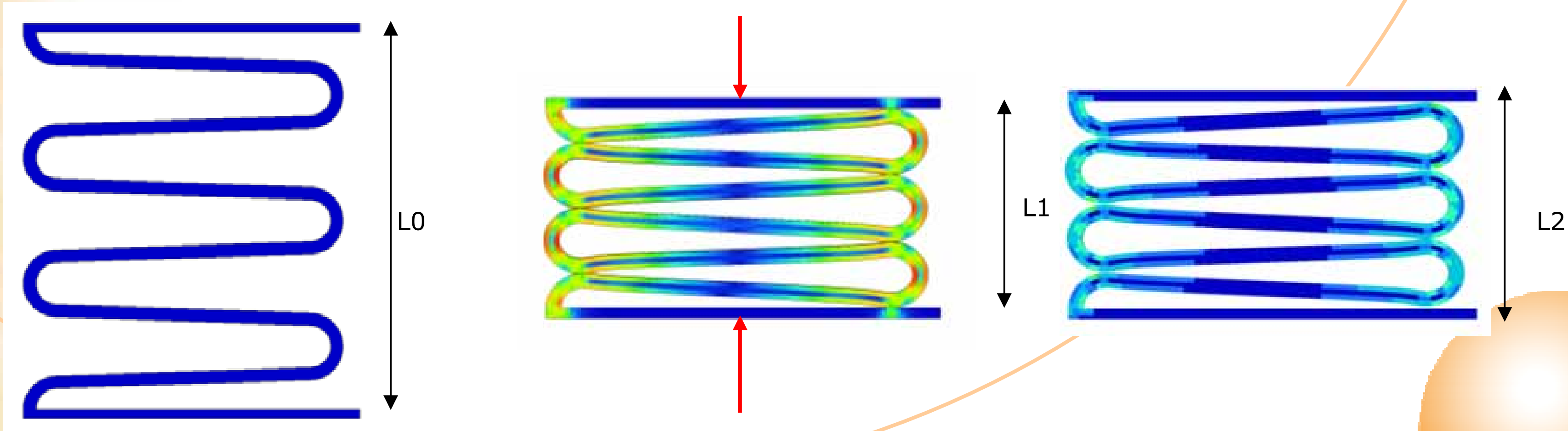
1. Optimization in 2D

1. Crimping and recoil simulation

- Compression of one stent pattern
  - Imposed displacement
- Relaxation
  - Spring back option (implicit)
- Recoil computation :

$$Re\ (\%) = \frac{[L1\ \text{after crimping} - L2\ \text{after relaxation}]}{L1\ \text{after crimping}}$$

Design optimization
to reduce recoil (%)



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SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

2. Traction and recoil simulation

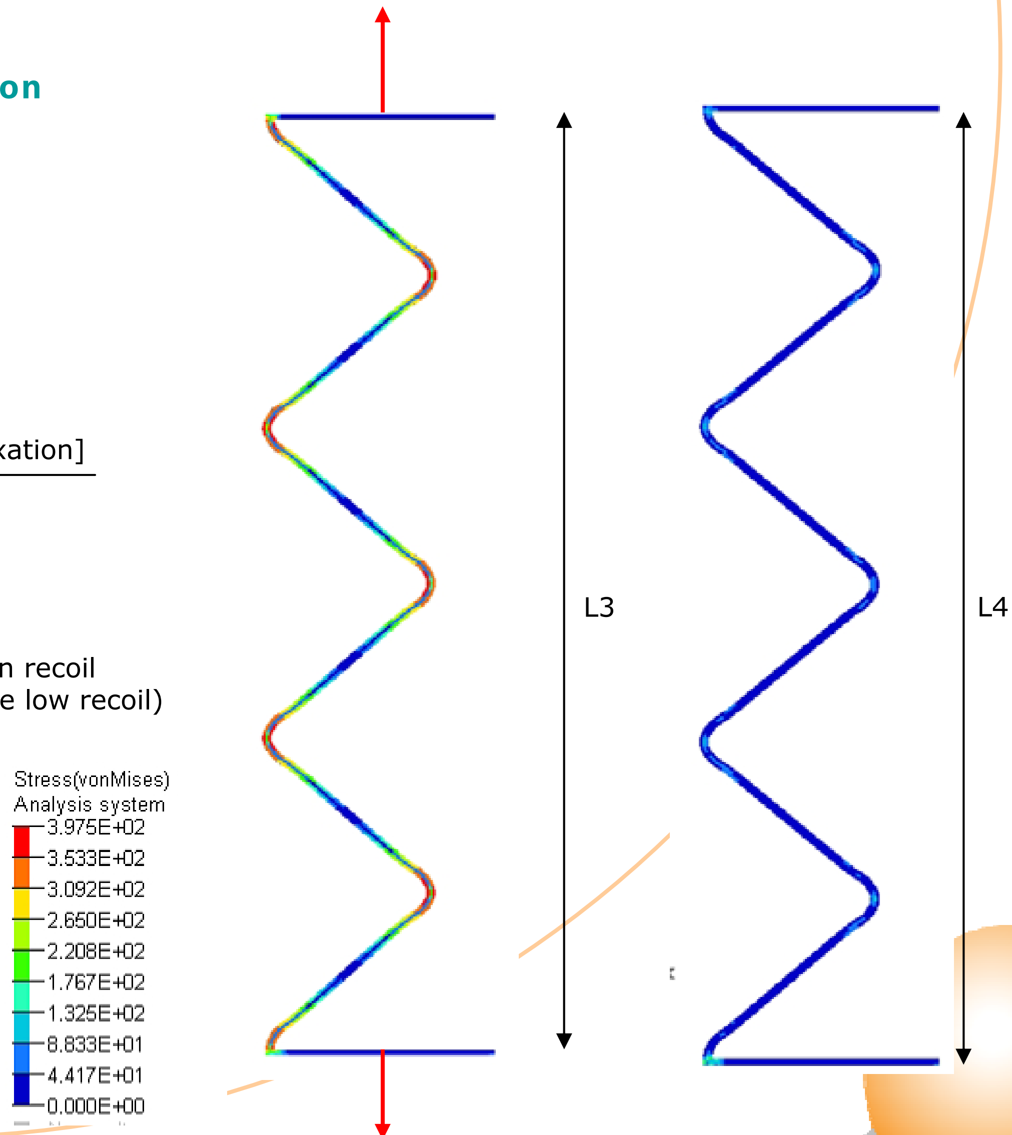
- Traction of one stent pattern
  - Imposed displacement

- Relaxation
  - Spring back option (implicit)

- Recoil computation:

$$Re\ (\%) = \frac{[L3\ \text{after traction} - L4\ \text{after relaxation}]}{L3\ \text{after traction}}$$

Remark: Crimping recoil is more important than traction recoil (expansion induces important strain and in consequence low recoil)



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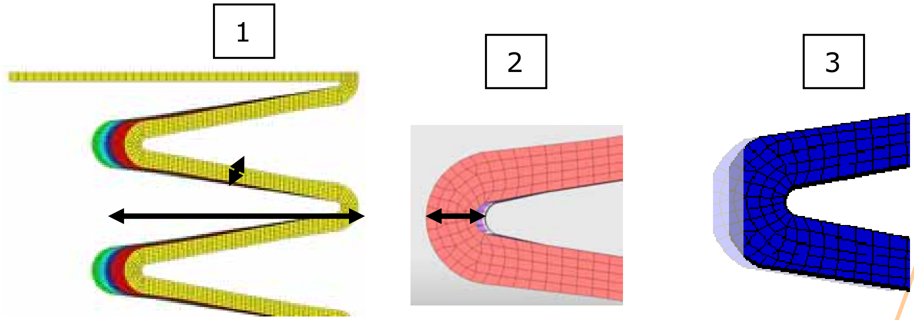
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

3. Design variables

- Strut length and thickness (1)
- Angle width (2)
- Angle design (3)



Optimization study:

Design n°	Design variables				Results	
	Slot length	**Thickness**	**Width**	**Angle design**	**Recoil %**	**Stress (MPa)**
1	L1	T1	W1	D1	R1	S1
2	L2	T1	W2	D1	R2	S2
3	L1	T2	W1	D1	...	...
Etc.	...	...	...	...	...	...

Best configuration in 2D tests
- lesser recoil
- no stress concentration
- (no rupture)

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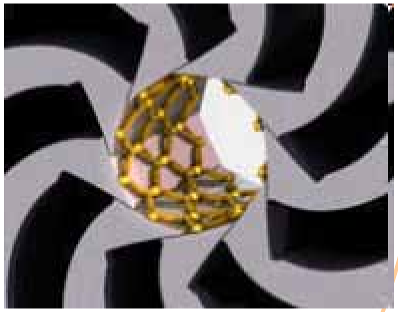
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

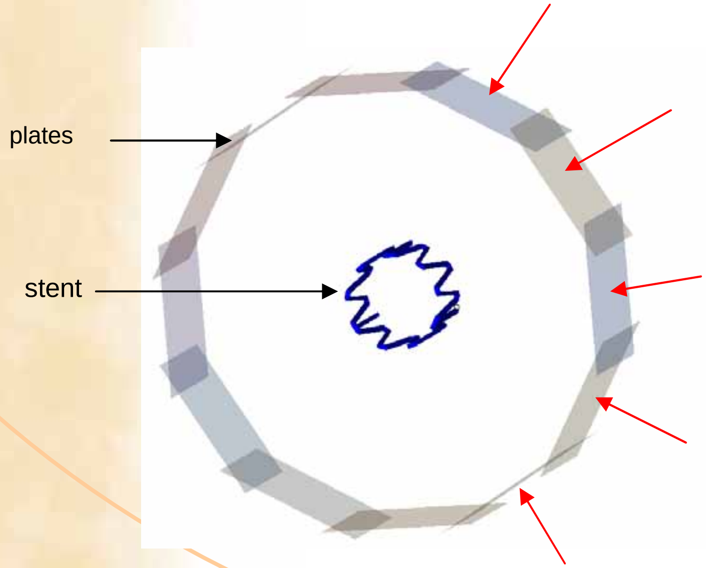
2. 3D configuration : Checking and validation

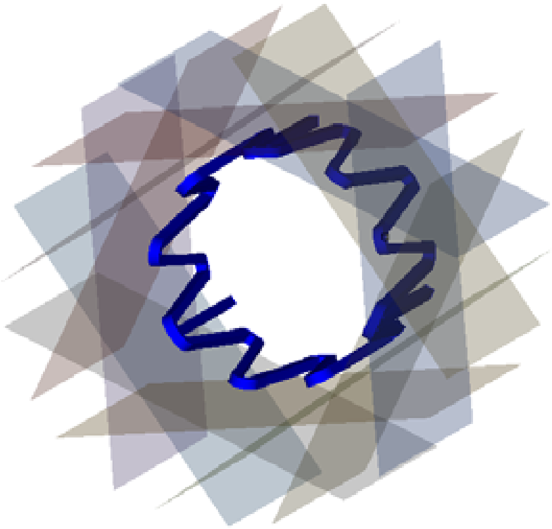
1. Crimping simulation

- Similar test to experimental method to obtain stent radial compression :
  - 12 plates in rigid body
  - Imposed displacement on each plate to obtain radial compression
  - Interfaces between stent/plate

Experimental protocol







– Initial stent diameter : 4.5 mm
– Final stent diameter : 2 mm

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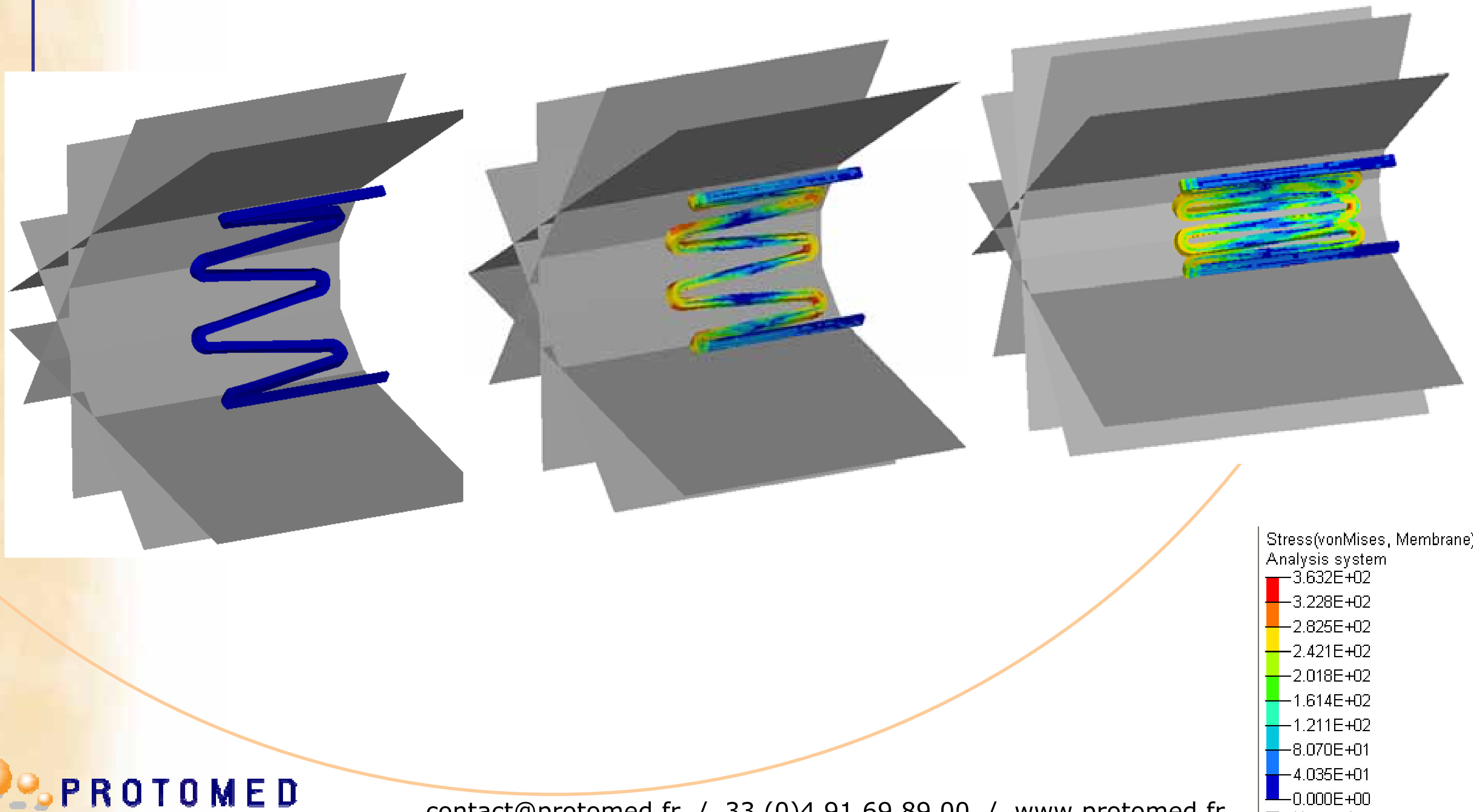
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

Results visualization for crimping (third of stent)



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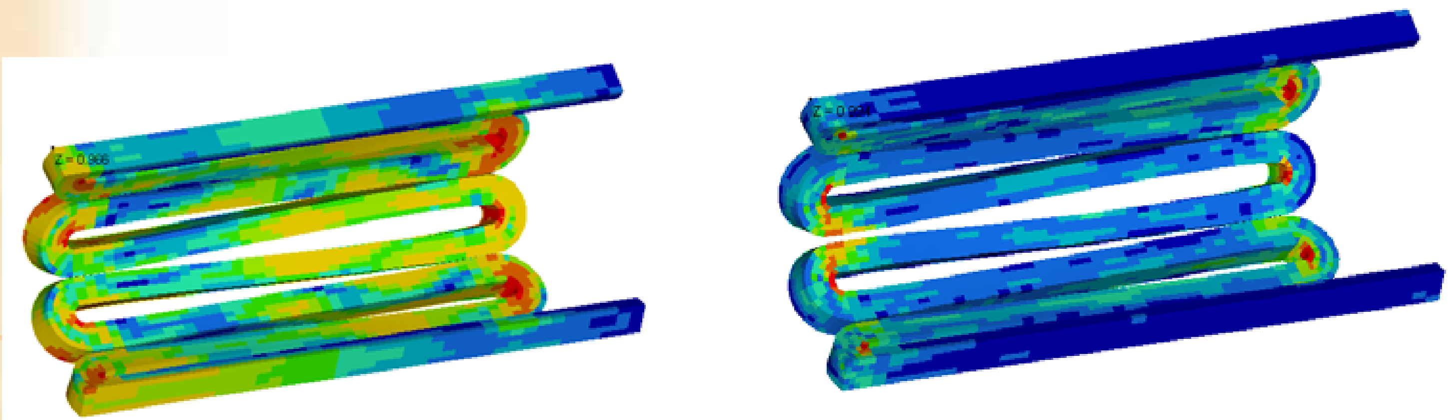
2. Recoil after crimping simulation

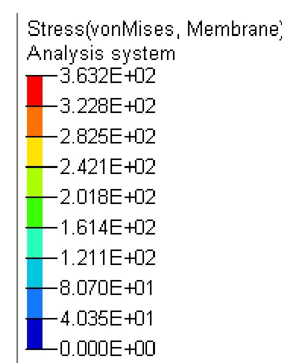
- From a second run after the crimping stage
- Suppression of plates and interfaces between stent and plates
- Use of implicit code with /SPRINGBACK option
  - Stress relaxation
  - Strain and radial displacement due to stress relaxation

- Recoil computation:

$$Re\ (\%) = \frac{[\Phi \text{ stent after crimpring} - \Phi \text{ stent after relaxation}]}{\Phi \text{ stent after crimping}}$$

Results visualization for recoil (third of stent)



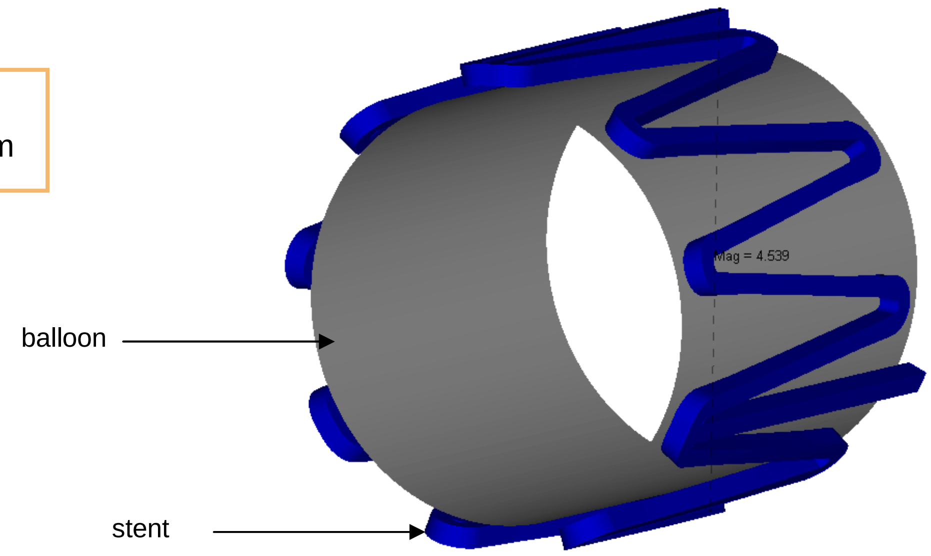


SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

3. Deployment simulation

- Similar test to real method to obtain stent radial inflation :
  - A balloon located inside the stent
  - Imposed Pload on the balloon
  - Interfaces between balloon/stent
  - Simulation using Radioss implicit code

– Initial stent diameter : 4.5 mm
– Final stent diameter : between 12 and 16 mm



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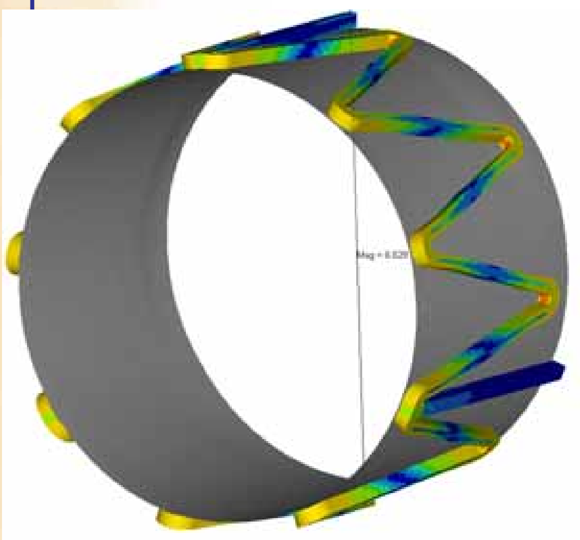
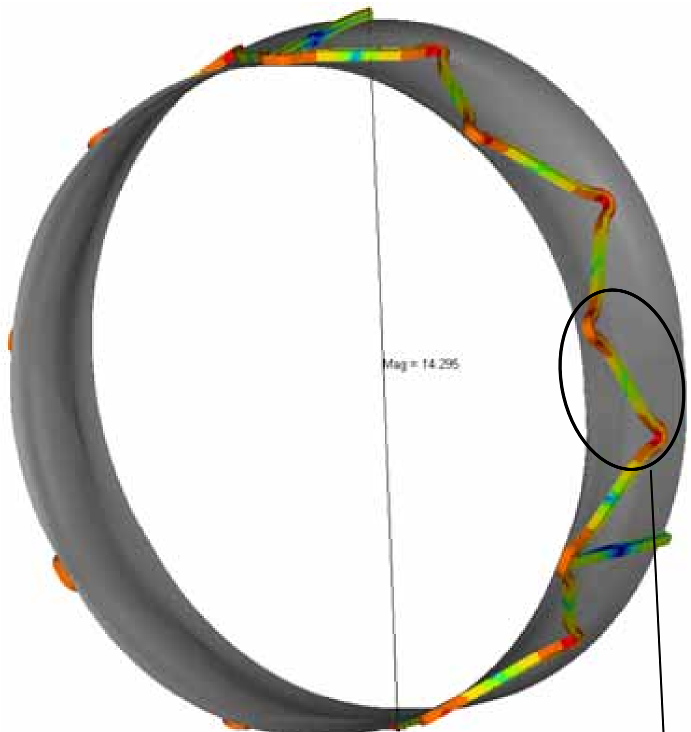
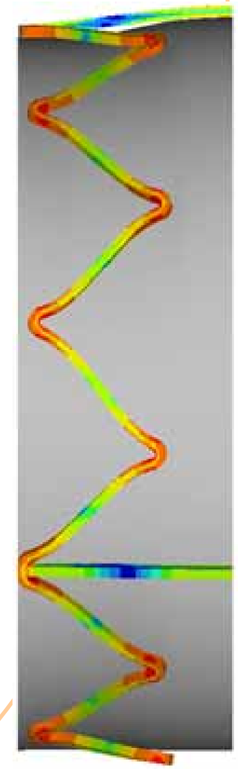
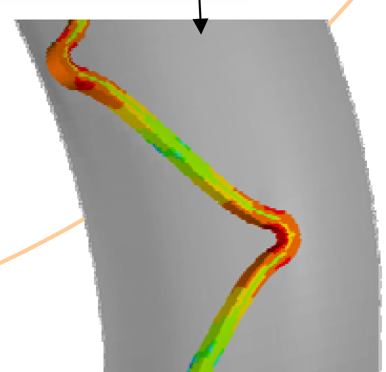
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

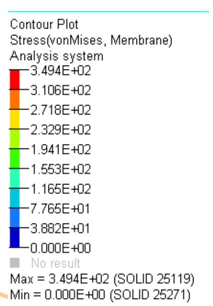
Results visualization for inflation











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SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

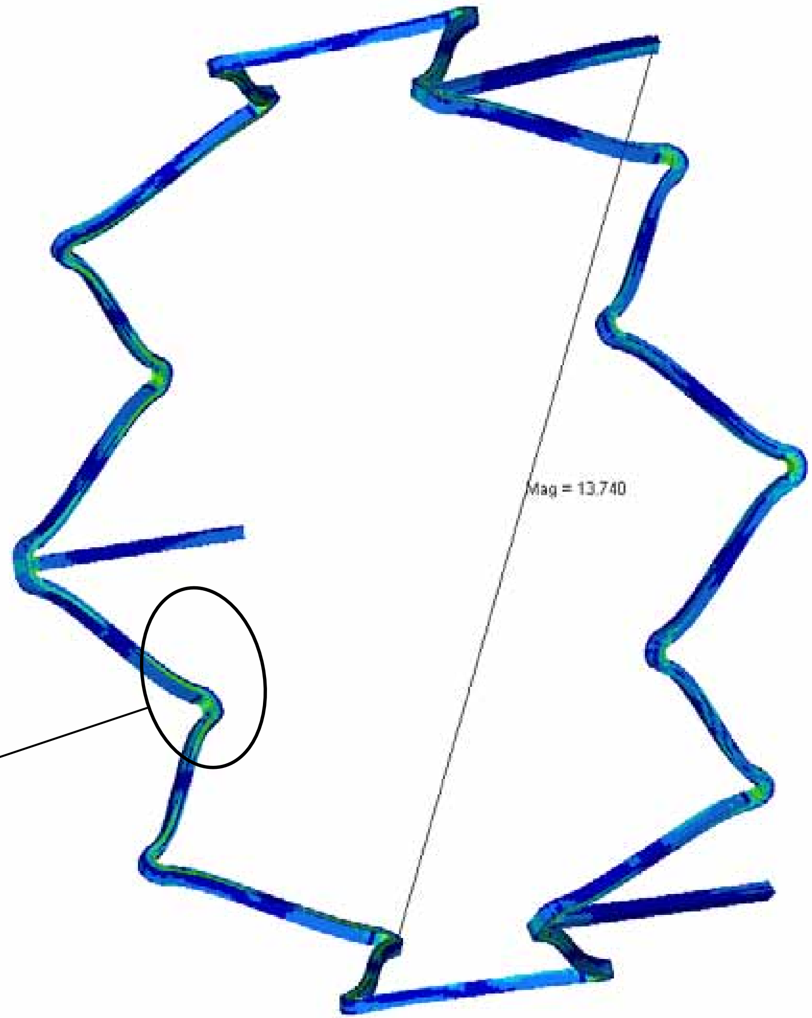
4. Recoil after deployment simulation

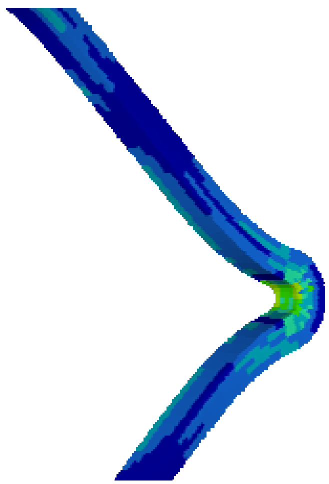
- From a second run after deployment stage
- Balloon and interfaces suppression
- Use of implicit code with /SPRINGBACK option
  - –Stress relaxation
  - –Strain and radial displacement due to stress relaxation

- Recoil computation :

$$Re\ (\%) = \frac{[\Phi \text{ stent after deployment} - \Phi \text{ stent after relaxation}]}{\Phi \text{ stent after deployment}}$$

Results visualization for inflation recoil

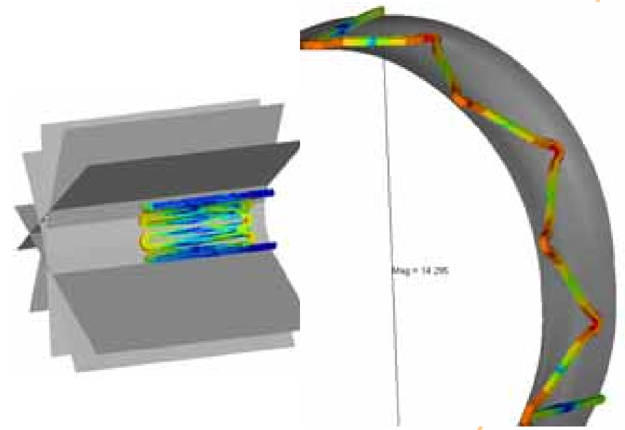




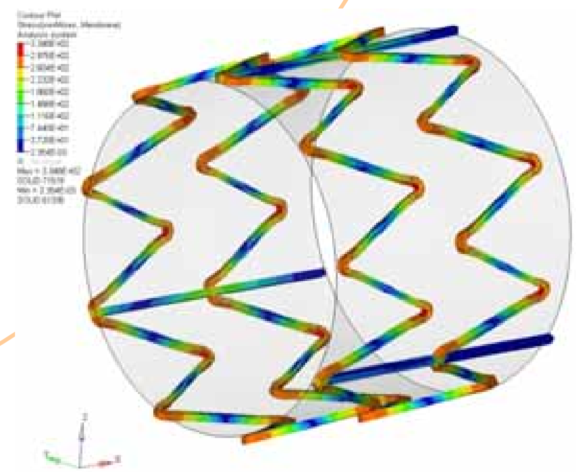
SIMULATION IN CARDIOVASCULAR STENT DEVELOPMENT

Conclusion and perspectives

- Stent design can be improved through numerical simulations
  - 2D optimization of stent pattern
  - 3D checking and validation (compression and expansion)



- Optimization is based on recoil reduction
  - Crimping recoil is more important than expansion recoil
- Validation is based on real conditions
  - Compression plates
  - Inflated balloon
- Perspectives
  - Radial stiffness study by taking into account artery reaction (during inflation)
  - Complex stent design (last generation material, specific design, etc)



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